# GOVERNMENT OF INDIA
# SCIENCE AND TECHNOLOGY
# LOK SABHA

UNSTARRED QUESTION NO:631
ANSWERED ON:24.11.2006
ESTABLISHMENT OF BIOTECH CLINICAL RESEARCH TRAINING CENTRES
Tripathy Shri Braja Kishore

**Will the Minister of SCIENCE AND TECHNOLOGY be pleased to state:**

(a) Whether the Government proposes to establish Biotech Clinical Research Training Centres in the country ;

(b) If so, the details and the salient features of such centres ;

(c) The aims and objectives for establishing such research centres; and

(d) The time by which these are likely to be established ?

## Answer

MINISTER OF SCIENCE & TECHNOLOGY AND MINISTER OF EARTH SCIENCES (KAPIL SIBAL)

(a) Yes Sir.

(b) & (c) The Clinical Research Training Centres will be established with an aim to conduct Short Term Training for physicians working in public institutions and in small and medium size industry on Clinical Research as relevant to development and evaluation of diagnostic, predictive and therapeutic modalities, implants and devices. Each centre is expected to conduct atleast 2 workshops a year with about 20 participants with a duration of 7 and 14 days each. The workshop content will include pre-clinical (toxicological studies) and clinical training design, clinical trial implementation, data management and analysis, regulatory requirement and documentation, concept of bioequivalence for pharma and biotech. products, Assay validation for product valuation, ethical issues and reporting trial results. The workshops are intended to be hands-on so that real skill transfer is accomplished.

(d) The centres are likely to be established during the current financial year.